PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
BW276R/RGR		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IT 03/00206	04.04.2003	04.04.2003
International Patent Classification (IPC) or both national classification and IPC		
A61B1/005		
Applicant		
UNIVERSITA' CATTOLICA DEL SACRO CUORE et Al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 7 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
14.04.2004	28.04.2005
Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Rivera Pons, C Telephone No. +49 89 2399-6063

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IT 03/00206

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

3-8	as originally filed
1, 2, 2a	received on 04.01.2005 with letter of 30.12.2004

Claims, Numbers

1-34	received on 04.01.2005 with letter of 30.12.2004

Drawings, Sheets

1/5-5/5	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-34
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-34
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-34
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document:

D1: US-A-5 025 778 (OPIE DECEASED ERIC A ET AL) 25 June 1991 (1991-06-25)

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and shows an endoscopic instrument having a flexible and elongate main body that houses a vision device, comprising a first and a second working arms for the use of tools apt to be operated independently.

The subject-matter of claim 1 differs from this known device in that the first and second working arms are transversally movable with respect to said main body, moving away and or nearing the one with respect to the other.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as to provide a device allowing more freedom of movement to the working arms.

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) because none of the available documents discloses nor suggests such a solution.

Claims 2-34 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

TITLE

ENDOSCOPIC INSTRUMENT

DESCRIPTION

The present invention refers to an endoscopic instrument, in particular to an advanced endoscope particularly useful for the non-invasive treatment of some digestive system pathologies.

To date, nearly every endoscopic instrument is made according to a common and time-honored architecture.

Image management has evolved, also due to the normal taking over of new technologies, however instrument mechanics and architecture remained the same.

Front vision endoscopes (e.g. the common gastroscope or the colonscope), and side vision instruments (the duodenoscope) are known.

Besides from the above, miniaturized endoscopes (e.g. cholangioscope) in all reproducing the latter were made.

Common denominator of all known instruments for digestive endoscopy is the presence of a single working channel (it also having a front or side exit) always having a direction consensual to the instrument body. In fact, such channel is internal to the endoscope body and passively submitting to its motions. The working channel allows the use of tools and/or of other accessories like pincers, balloons, extraction baskets or lancets for carrying out therapeutic maneuvers.

USA Patent n. 5,025,778 relates to an endoscope with a plurality of working channels and a vision apparatus. The working arms inserted in the working channels, can move according a longitudinal direction and can operate in a cooperative relationship. Nevertheless, the arms of such device cannot operate complex movements and for such reason the use of device does not result in a realistic reproduction of the classical surgery technique.

To date, the therapeutic scope of digestive endoscopy covers treatments like, e.g. the draining of biliary lithiasis, the treatment of chronic pancreatitis, the palliation of biliary tract neoplastic stenoses by positioning prostheses, the resection of incipient neoplastic transformation areas (e.g. mucosectomy) or of adenomatous areas (e.g. ampullectomy, polipectomy).

To date, also the treatment of bleeding, the dilation of benign stenoses and the reduction of gastroesophageal reflux are carried out by endoscopy.

However, the great limitation of operative endoscopy remains that of not allowing the resection of wider areas of organs, as a single working channel having reduced mobility would not allow managing potential complications.

For these and other situations laparoscopic or laparotomic surgery has to be resorted to.

This however increases costs, lengths of hospital stay, and the general discomfort of the patient, who is unable to choose effective non-invasive and conservative techniques.

Object of the present invention is to solve the described known-art problems, providing an endoscopic instrument having a flexible and elongate main body that houses a vision device for taking images of an organ internal area, comprising a first working arm for the use of tools and a second working arm for the use of tools apt to be operated independently with respect to said first working arm, characterized in that said first and second working arm are transversally movable with respect to said main body, moving away and/or nearing the one with respect to the other.

The instrument according to the present invention is an operative endoscopic device having advanced functions and an application scope lying between the endoscopic and the laparoscopic surgery fields.

The main advantage of an instrument according to the

present invention, with respect to the known-art endoscopic instruments, is provided by the fact that it allows to endoscopically treat a range of pathologies that at present are treatable only surgically, thereby giving surgical/therapeutic ends to a specialty originally meant to have substantially diagnostic aims.

Hence, an instrument according to the present invention allows to transfer the features and the advantages of some surgical techniques, especially of modern laparoscopy, to the field of endoscopy.

CLAIMS

1. An endoscopic instrument (10) having a flexible and elongate main body (11) that houses a vision device (22) for taking images of an organ internal area, comprising a first working arm (21) for the use of tools and a second working arm (23) for the use of tools apt to be operated independently with respect to said first working arm (21), characterized in that said first and second working arm (21, 23) are transversally movable with respect to said main body (11), moving away and/or nearing the one with respect to the other.

2. The instrument according to claim 1, wherein said main body (11) comprises an annular metal skeleton (12) coated with a rubber material sheath (13).

3. The instrument according to claim 1 or 2, further comprising first handling means of said main body.

4. The instrument according to claim 3, wherein said first handling means comprises one or more tie rods mechanically operated by a user.

5. The instrument according to claim 3 or 4, wherein said first handling means comprises first motion actuating and controlling devices of electronic and/or electromechanical type.

6. The instrument according to any one of the claims 1 to 5, wherein each of said first and second working arm (21, 23) are flexible.

7. The instrument according to any one of the claims 1 to 6, wherein each of said first and second working arm (21, 23) comprises a respective annular metal skeleton coated with a rubber material sheath.

8. The instrument according to any one of the claims 1 a 7, wherein each of said first and second working arm (21, 23) is apt to slide longitudinally with respect to said main body (11), independently the one from the other.

9. The instrument according to any one of the claims 1 to 8, further comprising second handling means of said first and second working arm (21, 23).

10. The instrument according to claim 9, wherein said second handling means comprises one or more tie rods mechanically operated by a user.

11. The instrument according to claim 9 or 10, wherein said second handling means comprises second motion actuating and controlling devices of electronic and/or electromechanical type.

12. The instrument according to any one of the claims 1 to 11, wherein said main body comprises a central body (25), said vision device (22) being connected at the end thereof.

13. The instrument according to claim 12, wherein said first and second working arm (21, 23) are located on two opposite sides of said central body (25).

14. The instrument according to claim 12 or 13, wherein said first and second working arm (21, 23) are connected to said central body by one or more annular mechanisms (30), each of said mechanisms being apt to rotate about said central body (25).

15. The instrument according to claim 14, wherein each of said annular mechanisms (30) is made with an elastically connected mesh structure.

16. The instrument according to any one of the claims 1 to 15, wherein said vision device (22) comprises a camera.

17. The instrument according to claim 16, wherein said camera is of digital type.

18. The instrument according to any one of the claims 1 to 17, wherein said vision device comprises one or more lenses.

19. The instrument according to claim 18, wherein each of said lenses is apt to be handled so as to vary its tilt with respect to the vision device.

20. The instrument according to claim 19, comprising two tiltable lenses.

21. The instrument according to any one of the claims 18 to 20, comprising means for adjusting the position of said lenses.

22. The instrument according to claim 21, wherein said adjusting means are of mechanic type, comprising a tie rod system operable by a user.

23. The instrument according to claim 21, wherein said adjusting means are of electromechanical and/or electronic type.

24. The instrument according to any one of the claims 1 to 23, further comprising means (40) for processing and visualizing the images taken.

25. The instrument according to claim 24, wherein said processing and visualizing means are apt to provide stereoscopic images of the area taken.

26. The instrument according to any one of the claims 1 a 25, further comprising means for monitoring its position with respect to said organ.

27. The instrument according to claim 26, wherein said monitoring means comprises one or more signal transmitters positioned on said main body and one or more external receivers of said signals, said received signals being representative of the position of the instrument.

28. The instrument according to claim 27, wherein said transmitters comprise one or more magnetic field coils.

29. The instrument according to claim 27 or 28, wherein said transmitters comprise one or more transponders.

30. The instrument according to any one of the claims 1 to 29, further comprising means for controlling frictions between the instrument and said organ.

31. The instrument according to claim 30, wherein said means for controlling frictions comprises one or more pressure and/or force sensors.

32. The instrument according to claim 31, wherein one or more of said sensors is of piezoelectric type.

33. The instrument according to claim 31 or 32, wherein one or more of said sensors is of membrane type.

34. The instrument according to any one of the claims 26 to 32, further comprising means for graphically representing said position of the instrument with respect to the organ and said frictions.

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☒ BLACK BORDERS
- ☒ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☒ BLURED OR ILLEGIBLE TEXT OR DRAWING
- ☒ SKEWED/SLANTED IMAGES
- ☐ COLORED OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REPERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.
As rescanning documents *will not* correct images problems checked, please do not report the problems to the IFW Image Problem Mailbox